4164-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2023-N-1506]**

# Methodological Challenges Related to Patient Experience Data; Summary of Received Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a summary on the comments received for the "Methodological Challenges Related to Patient Experience Data; Request for Information and Comments" notice published on May 2, 2023. The input received in response to the Request for Information will help FDA plan two public workshops focused on methodological challenges and will help FDA identify priorities for future work.

**FOR FURTHER INFORMATION CONTACT:** Ethan Gabbour, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6306, Silver Spring, MD 20993, 301-796-8112, Ethan.Gabbour@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Under the seventh iteration of the Prescription Drug User Fee Act, incorporated as part of the FDA User Fee Reauthorization Act of 2022, FDA committed to facilitate the advancement and use of systematic approaches to collect and utilize robust and meaningful patient and caregiver input that can more consistently inform drug development and, as appropriate, regulatory decision making. This included issuing a Request for Information (RFI) available at https://www.federalregister.gov/documents/2023/05/02/2023-09265/methodological-challenges-related-to-patient-experience-data-request-for-information-and-comments to elicit public input

on methodologic challenges related to patient experience data encountered by stakeholders, and other areas of greatest interest or concern to public stakeholders.[1] The RFI was published on May 2, 2023, and the public comment period was open until July 3, 2023. A summary of the comments received can be found in the in the public docket or by going to https://www.regulations.gov and entering the following docket number: FDA-2023-N-1506.

## II. Electronic Access

Persons with access to internet may obtain the summary within the public docket at https://www.regulations.gov/docket/FDA-2023-N-1506.

Dated: December 8, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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[1] The Federal Food, Drug, and Cosmetic Act, as amended by the 21st Century Cures Act (Pub. L. 114–255) and the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52), defines patient experience data as data that are collected by any persons (including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers and drug manufacturers) and are intended to provide information about patients' experiences with a disease or condition, including the impact (including physical and psychosocial impacts) of such disease or condition or a related therapy or clinical investigation and patient preferences with respect to treatment of the disease or condition.